

**Maryland Board of Pharmacy
Public Board Meeting
Minutes**

Date: August 21, 2013

Name	Title	Present	Absent	Present	Absent
Board Committee					
Bradley-Baker, L.	Commissioner	✓		1	1
Finke, H.	Commissioner/Secretary	✓		2	0
Gavgani, M. Z.	Commissioner/Treasurer	✓		2	0
Israbian-Jamgochian, L.	Commissioner/President		✓	1	1
Jones, David H.	Commissioner	✓		2	0
Rochester, C.	Commissioner	✓		1	0
Roy, S.	Commissioner	✓		1	0
Smith, J.	Commissioner		✓	0	2
Souranis, M.	Commissioner	✓		2	0
St. Cyr, II, Z. W.	Commissioner	✓		2	0
Board Counsel					
Bethman, L.	Board Counsel	✓		2	0
Felter, B.	Staff Attorney	✓		2	0
Board Staff					
Naesea, L.	Executive Director		✓	1	1
Wu, Y.	Compliance Manager		✓	0	2
Waddell, L.	Licensing Manager	✓		2	0
Gaither, P.	Administration and Public Support Manager	✓		2	0
Jeffers, A.	Legislation/Regulations Manager	✓		2	0
Johnson, J	MIS Manager	✓		2	0

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
I. Executive Committee Report(s)	A. H. Finke. Board Secretary	<p><i>Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.</i></p> <ol style="list-style-type: none"> H. Finke called the Public Meeting to order at 9:42 a.m. H. Finke requested all meeting attendees to introduce themselves, to sign the guest log and to indicate whether they would like continuing education credits. Members of the Board with any conflict of interests relating to any item on the agenda were advised to notify the Board. H. Finke reported that all handouts were to be returned by attendees when they leave the meeting. H. Finke acknowledged Howard Schiff for his 15 years of service with MPHA and noted that an open house retirement party will be held on September 10, 2013 from 11 a.m.to 2:00 p.m. at MPHA, Please RSVP through the MPHA website. Review and approval of July 17, 2013 public board meeting minutes. Approval of July 17, 2013 public board meeting minutes was approved as submitted. H. Finke acknowledged and welcomed two new Board Commissioners, Charmaine Rochester and Sajal Roy. 	<p>Motion by to approve the July 17, 2013, public board meeting minutes as presented. Motion was seconded by M. Souranis.</p>	<p>Motion was approved.</p>
II. Executive	A. Executive	1. Operations Updates – Operation updates will be presented		

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Director's Report	Director, L. Naesea	<p>by Executive Director, LaVerne G. Naesea at the Board's September Public Board Meeting as Ms. Naesea was not present at the meeting.</p> <p>2. Meeting Updates - Meeting updates will be presented by Executive Director, LaVerne G. Naesea at the Board's September Public Board Meeting.</p>		
B. Administration & Public Support	Administration & Public Support Manager, P. Gaither	<p>1. Personnel Updates</p> <p>The Board has recruited for its 50% pharmacist position. A tentative selection has been made and the Board is waiting on approval of the salary. If approved, an October 2, 2013 start date is planned. The Office Secretary I for the Licensing Unit position vacancy has been filled and the start date for that position is slated for September 4, 2013. The six month TE position in the Licensing Unit has ended, however, some of those functions will be met by the newly recruited Licensing Unit Secretary.</p>		
C. Management Information Systems	MIS Manager, John Johnson	<ul style="list-style-type: none"> No update this month as MIS Manager John Johnson was not present due to involvement in Board business 		
D. Licensing	L. Waddell, Licensing Manager	<p>Monthly Statistics for July, 2013.</p> <p>Pharmacists:</p> <ul style="list-style-type: none"> New Applications – 207 Renewals – 350 Total Licensed – 9607 		

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		<p>Pharmacists Administer Vaccinations:</p> <ul style="list-style-type: none"> New Applications – 75 Renewals – 0 Total Certified - 3231 <p>Technicians:</p> <ul style="list-style-type: none"> New Applications – 139 Renewals – 236 Total Registered –8525 this seems low, please double check with LaToya <p>Student Technicians</p> <ul style="list-style-type: none"> New Applications – 49 Renewals – 2 Total Registered – 806 <p>Pharmacies:</p> <ul style="list-style-type: none"> New Applications – 22 Renewals – 0 Total Pharmacies- 1920 <p>Distributors:</p> <ul style="list-style-type: none"> New Applications – 13 Renewals – 132 Total – 1075 		
E. Compliance	C. Jackson, Compliance Secretary	<p>1. Monthly Statistics for July, 2013</p> <p><u>Complaints & Investigations:</u></p> <p>New Complaints- 36</p> <p>Resolved (Including Carryover) – 32</p> <p>Final disciplinary actions taken – 8</p> <p>Reversal – 0</p>		

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	Gil Cohen, PEAC	<p>Summary Actions Taken – 1</p> <p><u>Inspections:</u> 154 Annual Inspections- 138 Opening Inspections- 9 Closing Inspections - 0 Relocation Inspections- 0 Board Special Investigation Inspections – 7</p> <ul style="list-style-type: none"> • Total Pharmacist Rehabilitation Committee Clients – 19 • Pharmacist Clients – 18 • Technician Clients – 0 • Pharmacy Student Clients – 0 • Clients Monitored by Board Req. PEAC Assistance – 1 • Drug Testing Results – 26 • Number of Positive Results – 0 		
F. Legislation & Regulations	A. Jeffers, Legislation & Regulations Manager	<p><u>REGULATIONS:</u></p> <p>10.34.03 – Inpatient Institutional Pharmacies Published June 28, 2013. No comments received. This is the Decentralized Pharmacy regulatory revision. The Board considered a delayed effective date for implementation. The date the Board approved is May 31, 2014. The Notice of Final Action will reflect the May 31, 2014 effective date.</p> <p>It was requested that this be announced in a newsletter article.</p> <p>10.34.19 Sterile Pharmaceutical Compounding Board approved draft revisions at May 15, 2013 Board Meeting. Revised proposal sent to the Secretary for initial comment May 23, 2013. Secretary attended June 19, 2013 Board Meeting. Public Notice for initial comments posted July 11, 2013. Subcommittee met July 30th.</p>	<p>Motion by D. Jones to have May 31, 2014 the delayed effective date for implementation of COMAR 10.34.03. Motion was seconded by M. Souranis.</p>	<p>Motion was approved.</p>

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		<p><i>Revised regulations and responses to comments received, to be presented in September.</i></p> <p>10.34.22 – Licensing of Wholesale Prescription Drug or Device Distributors Submitted July 23, 2013 to DHMH for sign-off and publication.</p> <p>Linda Bethman suggested that the proposal be returned to the Practice Committee for discussion of further revisions.</p> <p>10.34.23 Pharmaceutical Services to Patients in Comprehensive Care Facilities Published May 31, 2013. 30 day comment period to follow. No Comments. Notice of Final Action in sign-off process.</p> <p>10.34.32 Pharmacist Administration of Vaccinations Meeting July 16th with Infectious Disease Program.</p> <p>Board approval requested for the proposal:</p> <p><u>Proposed Revisions - 10.34.32 082113</u></p> <p><u>Proposed.Revisions.10.34.32.tc.3 Jody 081613</u></p> <p>Most recent version received the night before was approved with the following revisions:</p> <p>.03 Requirements to Administer Vaccinations.</p> <p><u>Section E. has been returned to the chapter.</u></p> <p>"E. A pharmacy student in a Pharmacy Experiential Program, who has successfully completed a Board-approved certification course, may administer vaccinations under direct supervision of a licensed pharmacist who meets requirements in §A of this regulation."</p>	<p>COMAR</p> <p>10.34.22 referred back to Practice Committee to discuss further revisions.</p> <p>Motion by M. Souranis to approve revisions to COMAR 10.34.32, as stated in these minutes. Motion was seconded by D. Jones</p>	<p></p> <p>Motion was approved.</p>

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		<p>Even though Health Occupations Article, 12-508, Annotated Code of Maryland, does not specifically give pharmacy students the authority to administer vaccinations, the Maryland Pharmacy Act does allow students to perform the same duties, or scope of practice, as a pharmacist, so long as they are under the direct supervision of a pharmacist. This provides students real training in administration of vaccinations and is part of a pharmacy students internship in community and hospital pharmacies.</p> <p>.07 Approved Protocols.</p> <p><u>C.(7) has been deleted.</u></p> <p>"(7) Process for verification of prescription patients 11 - 17 years old;"</p> <p>Verification of valid prescriptions is what pharmacists do for every prescription that is received in the pharmacy. This is not necessary to be included in a protocol.</p> <p><u>C.(12)(f) has been revised to read:</u></p> <p><u>(f) Documentation:</u></p> <p><u>(i) Of at least one attempt to inform the patient's primary care provider or prescriber that the vaccination has been administered;</u> <u>or</u></p> <p><u>(ii) That the patient has no primary care provider.</u></p> <p><u>(g) Documentation of an attempt to inform the patient's primary care provider that the influenza vaccination has been administered may not be required.</u></p> <p>The Board members expressed concern because some patients do not have a primary care provider so it would be impossible for them make an attempt to contact the primary care provider. If the pharmacist ascertains that there is no primary care provider then the</p>		

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		<p>pharmacist will document that in the patient record.</p> <p>Additionally, a pharmacist Board Member, who has run influenza immunization clinics, expressed concern with the logistics of informing primary care providers when immunizing a very large group of individuals in a short period of time.</p> <p>.08 Fees.</p> <p>The Board referred Regulation .08 to the Practice Committee which will meet on August 28, 2013.</p> <p>Finally: It was asked if every pharmacist at a chain drug store or hospital would be required to sign a protocol. Yes, each individual pharmacist administering immunizations would have to sign a protocol.</p> <p>10.34.33 Prescription Drug Repository Program Proposal submitted May 22, 2013. In the DHMH sign-off process. To be reviewed again in the Practice Committee.</p> <p>10.13.01 Dispensing of Prescription Drugs by a Licensee Meeting with Dr. Herrera scheduled for July 29th at the Board Offices.</p> <p>Ratification of follow up letter to Dr. Herrera:</p> <p><u>Dispensing Prescribers Letter 8-5-2013</u></p> <p><u>The Board ratified the following letter:</u></p> <p>On behalf of the Maryland Board of Pharmacy, I am again writing to thank you for meeting with representatives on July 29, 2013 to discuss the proposed revisions to COMAR 10.13.01 and the available resources for inspections of prescribing dispensers at each of their office locations. Prior to the meeting, the Board received and reviewed the Division of Drug Control's White Paper on: Pharmacy Inspections. The Board expressed real concerns that certain data</p>	<p>COMAR 10.34.33 referred back to the Practice Committee for further review.</p> <p>Motion by Legislative Committee to ratify letter to Dr. Laura Herrera regarding COMAR 10.13.01, as stated in these</p>	<p></p> <p></p> <p>Motion was approved.</p>

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		<p>contained in that document did not reflect the data that the Board had previously captured from the Division of Drug Control's inspection reports. The reports may require further review, including but not limited to prescribing dispenser biennial inventories. Also, the Board emphasized again that prescriber dispensing sites should be subject to the same rigorous inspections as pharmacies in order to adequately protect the public.</p> <p>The Board also discussed the two recommendations presented in the White Paper. The first was that a more formalized communication process be established for exchanging information regarding inspections between the DDC and the Board. Further dialogue with the Division of Drug Control on this process will occur after the new DDC Director is in place. The second recommendation proposed that DDC inspect the primary practice site of a prescribing dispenser, and if a violation is uncovered, then the DDC would provide resources to inspect all of the operating practice sites associated with the particular prescribing dispenser's permit. The Board agreed with this process as an interim step while statutory changes (agreed to by all of the parties at the meeting) are promulgated to require the issuance of dispensing permits only to those practitioners who are 10 miles or greater proximity to a pharmacy. The ten (10) mile radius is consistent with the Maryland Medicaid regulations. COMAR 10.09.03.07. Board representatives further agreed to support certain exceptions being made to this requirement in consideration of possible limited access by certain members of such populations as elderly and/or disabled patients. No specific criteria was discussed at the meeting; however, Board representatives noted that any future agreed upon exceptions should also require the ability of a practitioner to dispense all of an excepted patient's prescribed medications from their offices since a patient determined to have limited access to a pharmacy would otherwise be required to visit a pharmacy to fill any prescription that the practitioner does not have at his office. All meeting participants agreed that the proposed statutory change would decrease the number of dispensing permits issued: thereby</p>	minutes. Motion was seconded by M. Souranis.	

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		<p>resolving Department concerns related to having limited resources to inspect all of the sites where dispensing permits were applied.</p> <p>To summarize below are agreed upon steps:</p> <p>1) The Board will remove the following bracketed words from the revised COMAR 10.1 3.01 .03E so that the regulations may move forward:</p> <p>E. A permit issued to a licensee shall be for a specific location and is non-transferable.</p> <p>This is a temporary measure until resources are reallocated after the 10 mile radius restriction becomes law.</p> <p>2) The Department and Board will seek Legislation in the 2014 Legislative Session that would restrict prescribers from dispensing prescription medications, with exceptions (to be determined), if there is a pharmacy within a 10 mile radius of the prescriber's practice site. Dr. Herrera indicated that the Department would most likely support this legislation. She will discuss with the Secretary within the week and circle back with the Board.</p> <p>3) The Board proffers any assistance and expertise to the DDC in deference to the radial framework that will serve as a focal point and as a tool for DHMH administratively in the tracking and monitoring of dispensing practice sites.</p> <p>4) A new director of the Division of Drug Control is expected to be on hoard within the month. Following her arrival, a schedule of formal and routine meetings will be established between the Division of Drug Control and the Board of Pharmacy to foster communication and sharing of inspection information.</p> <p>Once again the Board appreciates your taking time from your busy schedules to meet on these important issues. We look forward to hearing from you in the near future.</p> <p>Board approval requested for:</p> <p><u>Proposed-1-11 10.13.01 Revised 081613</u></p>		

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		<p>The Board approved the proposal for submission into the regulatory process.</p> <p><u>LEGISLATION:</u></p> <p>1) Consumer Board Members – Proposal submitted July 19, 2013.</p> <p>Anna Jeffers sought and received approval to send the proposed legislation to pharmacy associations listed in HO 12-202.</p> <p>2) Graduate Intern Legislation – Draft in the review process by Licensing and Disciplinary Committees.</p> <p>3) Naturopaths –</p> <p>David Jones reported on the August 20th Workgroup Meeting of the Naturopathic Doctors. He explained the criteria that will be considered by the Board of Physicians, or the legislature, when contemplating regulating another health profession.</p> <p>Board’s position on last year’s bill.</p> <p><u>sb0783F</u></p> <p>Practice recommends two changes:</p> <p>1) Add a pharmacist to the formulary committee;</p> <p>2) Page 13, Line 28 -</p> <p>(C) A LICENSE DOES NOT AUTHORIZE A LICENSEE TO:</p> <p>(1) PRESCRIBE, [DISPENSE,] OR ADMINISTER ANY CONTROLLED SUBSTANCE OR DEVICE IDENTIFIED IN THE FEDERAL CONTROLLED SUBSTANCES ACT, EXCEPT AS AUTHORIZED BY THE BOARD;</p> <p><u>and</u></p> <p><u>(2) DISPENSE ANY CONTROLLED</u></p>	<p>Motion by Legislative Committee to approve COMAR 10.13.01 for submission into the regulatory process. Motion was seconded by M. Souranis.</p> <p>Motion by Legislative Committee to approve changes to SB0783F, as stated in these minutes. Motion was seconded by M. Souranis.</p>	<p>Motion was approved.</p> <p>Motion was approved.</p>

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		<p><u>DANGEROUS SUBSTANCE.</u></p> <p>The Board approved the revisions and suggestions above for the 2013 Naturopath Legislation. This will be sent to Mark Woodard who is preparing the legislative report for the Board of Physicians.</p> <p><u>MEETINGS:</u></p> <p>2013 Telemedicine Task Force. Mitra Gavvani will be attending the Clinical Advisory Group Meetings and David Jones will be attending the Technology Solutions and Standards Advisory Group.</p> <p>http://mhcc.dhmdh.maryland.gov/hit/Telemedicine/Pages/telemedicine_main.aspx</p> <p>There will also be a Telemedicine Task Force Financial and Business Model Advisory Group. This advisory group will be meeting ad hoc and there are not any meetings scheduled at this time, although MHCC anticipates a handful of meetings to occur before the end of the year.</p> <p>Pharmacy Benefit Managers – Specialty Drug Interim Study in the House and Government Operations Committee</p> <p>Anna Jeffers reported briefly on the Meeting in Annapolis on August 20th. An overview was presented by Dr. Hynicka from the University of Maryland School of Pharmacy. A PBM Survey was discussed and concerns of independent pharmacies were presented by Dennis Rasmussen and Angelos Voxakis. Access, adherence to medications is of concern to pharmacists as many specialty drugs may only be received from mail order and often days late.</p> <p>Another meeting will be scheduled where Chairman Hammen would like to hear from patients who have had access issues. The Utilization Review Accreditation Commission (URAC) will be</p>		

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		invited to the next meeting as they accredit specialty pharmacies. Board members mentioned that NASP and ACHC also certify or accredit specialty pharmacies. Anna Jeffers will inform Linda Stahr of these other organizations		

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	H. Finke, Chair,	<p>Inquiries:</p> <p>1. Podiatric Medical Examiners</p> <p><u>Board of Podiatric Medical Examiners</u></p> <p><u>Draft Board Response – Podiatric Med Examiners</u></p> <p>The Board approved the following response:</p> <p>Thank you for contacting the Maryland Board of Pharmacy requesting that the Board of Pharmacy review the information submitted and inform you if there are any violations with regard to compounding requirements, requirements for approval by FDA and/or distribution of Fungasil by the podiatrist to his patients.</p> <p>Please be advised that Dr. Wayne Knoll is within the law to compound Fungasil for his own patients. If Dr. Knoll is compounding for specific patients and dispensing to his patients then he is required to obtain a dispensing permit from the Board of Podiatric Medical Examiners.</p> <p>If, however; Dr. Knoll is compounding this product and selling to individuals other than his patients or to other pharmacies, physicians, podiatrists, or health care facilities, then he is required to obtain a manufacturers permit from the U.S. Food and Drug Administration (FDA).</p> <p>2. Dr. Fasanella, Three Lower Counties Community Services & UMES</p> <p><u>DTM - referrals from NP and PA</u></p> <p><u>Draft Board Response – DTM – referrals from NP and PA</u></p> <p>The Board approved the following response:</p> <p>Thank you for contacting the Maryland Board of Pharmacy requesting the Board’s opinion concerning the inclusion of Nurse Practitioners and Physician Assistants within Drug Therapy Management. You had presented the Board with two possible scenarios:</p> <p>Pages 14 of 17</p>	<p>Motion by Practice Committee to approve draft Board response to Board of Podiatric Medical Examiners, as stated in these minutes. Motion was seconded by M. Gavvani.</p> <p>Motion by Practice Committee to approve draft Board response to Dr. Fasanella, as stated in these minutes. Motion was approved by M. Souranis.</p>	<p>Motion was approved.</p> <p>Motion was approved.</p>
III. Committee Reports				
A. Practice Committee		<p>1. Amend the physician-pharmacist agreement:</p> <p>a. The documentation submitted to the Board would state that a referral by a Nurse Practitioner would be considered a</p>		

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B. Licensing Committee	L. Bradley-Baker., Chair,	<p>1. Review of Pharmacy Technician Applications:</p> <p><u>None</u></p> <p>2. New Business:</p> <ul style="list-style-type: none"> David Morcos, – Applicant is asking for a waiver of the reactivation fee. Licensing Committee recommendation is to deny the request; Olufunke Sokan, – Applicant is asking for another extension of time to obtain social security number⁵. Licensing Committee recommendation is to deny the request. 	<p>Motion by Licensing Committee to deny the request of applicant David Morcos for a waiver of the reactivation fee. Motion was seconded by D. Jones.</p> <p>Motion by Licensing Committee to deny the request of applicant Olufunke Sokan for another extension of time to obtain social security number. Motion was seconded by M. Gavgani.</p>	<p>Motion was approved.</p> <p>Motion was approved.</p>
C. Public Relations Committee	Z. St. Cyr, II	<p>Public Relations Committee Update:</p> <ul style="list-style-type: none"> Public Outreach Events: <p>1. The Board participated at the Maryland ASCP meeting on Solomon’s Island last month and the attendees appreciated</p>		

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		<p>the Board's participation.</p> <p>2. The Board's annual CE Breakfast to be held October 6, 2013 is already completely booked we have a waiting list for that event. Radisson Cross Keys hotel indicated they would allow an increase of attendees from 150 to 200. The Board is currently looking for an alternative location to accommodate the high number of people on the waiting list. The Board will keep the public informed of any change in venue for the annual CE Breakfast);</p> <p>3. A reminder to all Board Commissioners and to the public that the Board of Pharmacy's September public board meeting will be held on Friday, September 20, 2013 at the University of Maryland Eastern Shore School of Pharmacy and will begin at 10:00 a.m. Janet Seeds will be sending information to the Board Commissioners as to hotel reservations. Information regarding the address and room number will be posted on the Board's website within the next few days. Thank you to the UMES School of Pharmacy for working with the Board on this meeting.</p> <p>4. The Board is proud to be a Silver Sponsor of the Maryland Pharmacists Association MTM (Medication Therapy Management) Summit which will be held on September 28 & 29, 2013 at Montgomery Park.</p>		
D. Disciplinary	M. Gavvani, Chair	Disciplinary Committee Update – No update this month.		
E. Emergency Preparedness Task Force	L. Bradley-Baker, Acting Chair	<p>Emergency Preparedness Task Force Update :</p> <p>The EPTF will participate in a statewide drill to be held September 24 -26, 2013. The Task Force members will be responsible for quality assurance of product to be shipped to a point of distribution</p>		

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		site. L. Bradley-Baker was pleased to announce and to welcome the Board's two newest Commissioners, Charmaine Rochester and Sajal Roy as members of the Emergency Preparedness Task Force..		
IV. Other Business & FYI	L. H. Finke, Secretary	There was no other business presented.		
V. Adjournment	H. Finke, Secretary	<p>The Public Meeting was adjourned at 11:28 <u>A.M.</u></p> <p>At <u>12:44 P.M.</u>, H. Finke convened a Closed Public Session to conduct a medical review of technician applications.</p> <p>C. The Closed Public Session was adjourned at 2:10 P.M. Immediately thereafter, H. Finke convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.</p>	<p>Motion by M. Souranis to adjourn the Public Board meeting pursuant to State Government Article 10-508)a)(13) and (7) for the purpose of engaging in medical review committee review deliberation regarding confidential matters in applications Meeting. The motion was seconded by D. Jones.</p>	Motion was approved.